UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,892	03/23/2005	Tatsuo Hoshino	21413 US C038435/0185654	4644

7590 12/15/2006

Stephen M. Haracz
Bryan Cave
1290 Avenue of the Americas
New York, NY 10104

EXAMINER	
FRONDA, CHRISTIAN L	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/528,892	HOSHINO ET AL.	
	Examiner	Art Unit	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/23/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-7 are pending and under consideration in this Office Action.

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are genus claims drawn to a genus of mutant recombinant microorganisms of the genus *Sinorhizobium* capable of producing vitamin B_6, and a genus of pdxJ genes of any nucleotide sequence and structure from any biological source. The scope of each genus includes many members with widely differing structural, chemical, and physiochemical properties including widely differing nucleotide sequences and biological functions. Furthermore, each genus is highly variable because a significant number of structural and biological differences between genus members exist.

The specification discloses that the coding region of the pdxJ gene from *S. meliloti* IFO14782, which encodes pyridoxol 5-phosphate synthase, was obtained using PCR primers of SEQ ID NO: 1 and SEQ ID NO: 2 (see Example 1 of the specification). The specification discloses *S. meliloti* IFO 14782/pVKP601, *S. meliloti* PY-C341K1, and *S. meliloti* PY-EGC1, which produced more pyridoxol compared to the parent strain *S. meliloti* IFO14782 (DSM 10226) (see Examples 1-5 and Table 1).

However, the specification does not describe and define any structural features and nucleotide sequences that are commonly possessed by members of the claimed genus of pdxJ genes. The specification fails to disclose other members of the claimed genus of pdxJ genes,

which are widely variant in their nucleotide sequences and structures and biological sources, other than the coding region of the pdxJ gene from *S. meliloti* IFO14782, which encodes pyridoxol 5'-phosphate synthase, obtained using PCR primers of SEQ ID NO: 1 and SEQ ID NO: 2. Furthermore, the specification fails to disclose additional mutant recombinant microorganisms as encompassed by the claimed genus of mutant recombinant microorganisms of the genus *Sinorhizobium* capable of producing vitamin B_6, which are widely variant in their physiological characteristics, functions, and/or structures. As such, the disclosure of *S. meliloti* IFO 14782/pVKP601, *S. meliloti* PY-C341K1, and *S. meliloti* PY-EGC1 of the claimed genus of mutant recombinant microorganisms is insufficient to be representative of the attributes and features common to all the members of the claimed genus. Thus, one skilled in the art cannot visualize or recognize the identity of the members of the genus.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v, Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. Therefore, the instant claims are not adequately described.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of a genus of recombinant microorganisms of the genus *Sinorhizobium* capable of producing vitamin B_6, and a genus of pdxJ genes of any nucleotide sequence and structure from any biological source.

Furthermore, the claims are rejected for the following additional reasons. The claims encompass any pdxJ gene of any nucleotide sequence and structure from any biological source. Gene elements which are not particularly described, including promoter regions, regulatory elements, and untranslated regions, are essential to the function of the claimed invention since the claims recite the term "gene". The art indicates that the structure of these gene elements are empirically determined. Therefore, the structure of these elements which applicants considers as being essential to the function of the claim are not conventional in the art.

There is no known or disclosed correlation between the coding region of a polynucleotide encoding pyridoxol 5-phosphate synthase and the structure of the non-described promoter

regions, regulatory elements, and untranslated regions. Thus, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of any pdxJ gene.

5. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The claims are directed toward any mutant recombinant microorganisms of the genus *Sinorhizobium* capable of producing vitamin B_6 having any recombinant plasmid with any pdxJ gene of any nucleotide sequence and structure from any biological source.

The specification discloses that the coding region of the pdxJ gene from *S. meliloti* IFO14782, which encodes pyridoxol 5-phosphate synthase, was obtained using PCR primers of SEQ ID NO: 1 and SEQ ID NO: 2 (see Example 1 of the specification). The specification discloses *S. meliloti* IFO 14782/pVKP601, *S. meliloti* PY-C341K1, and *S. meliloti* PY-EGC1, which produced more pyridoxol compared to the parent strain *S. meliloti* IFO14782 (DSM 10226) (see Examples 1-5 and Table 1).

However, the specification does not provide guidance, prediction, and working examples for making any mutant recombinant microorganisms of the genus *Sinorhizobium* capable of producing vitamin B_6 having any recombinant plasmid with any pdxJ gene of any nucleotide sequence and structure from any biological source.

Thus, an undue amount of trial and error experimentation must be preformed where such experimentation involves searching and screening a vast number of biological sources for any pdxJ gene of any nucleotide sequence and structure, transforming the pdxJ gene into any microorganism of the genus *Sinorhizobium*, mutating the microorganism with any mutagenic agent, and screening for mutants that are capable of producing vitamin B_6 , wherein said mutants have acquired histidine requirement or glycine resistance or combinations thereof. General teaching regarding screening and searching for the claimed invention is not guidance for making the claimed invention.

The examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific biological source and nucleotide sequence of the pdxJ gene.

Without such a guidance, the amount of experimentation left to those skilled in the art to make the invention is undue and well outside of routine experimentation.

Regarding claims 3, 5, and 7 it is apparent that the plasmid pVK100 and the microorganism *Sinorhizobium meliloti* PY-EGC1 are required to practice the claimed invention. As such the said plasmid and microorganism recited in the claims must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 USC § 112, first paragraph, may be satisfied by a deposit of the plasmids.

The process disclosed in the specification to make the plasmid and microorganism does not appear to be repeatable. The nucleotide sequences of the plasmid vectors used to make pVK100 are not fully disclosed, nor have all the nucleotide sequences required for their construction been shown to be biblically known and freely available. The specification does not disclose a repeatable process to obtain the plasmid and microorganism and it is not apparent if the nucleotide sequences are readily available to the public. It is not apparent if the source materials to make the plasmid and microorganism recited in claims 3, 5, and 7 are both known and readily available to the public.

An enabling deposit of the plasmid pVK100 and the microorganism *Sinorhizobium meliloti* PY-EGC1 may overcome the rejection. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicant, or a statement by an attorney of record over his/her signature and registration number, stating that the specific microorganism has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809 and MPEP 2402-2411.05, the applicant may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his/her signature and registration number, showing that:

(1) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(2) all restriction upon availability to the public will be irrevocably removed upon granting of the patent;

(3) the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(4) the deposit will be replaced if it should ever become inviable.

Conclusion

6. No claim is allowed.

7. The following reference made of record and not relied upon is considered pertinent to applicants' disclosure: Laber et al. (FEBS Lett. 1999 Apr 16;449(1):45-8) teach a process for producing pyridoxine 5'-phosphate using recombinant PdxA and PdxJ produced by *E. coli* host cells.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday- Friday from 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N. Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CLF

TEKCHAND SAIDHA
PRIMARY EXAMINER